

EXHIBIT B

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION THIS DOCUMENT RELATES TO WAVE 1 / TVT-O CASES	Master File No. 2:12-MD-02327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
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RULE 26 EXPERT REPORT OF DR. ABBAS SHOBEIRI

The following report is provided pursuant to Rule 26 of the Federal Rules of Civil Procedure. All of the opinions that I offer in this Report I hold to reasonable degree of medical or scientific certainty.

I. QUALIFICATIONS

Currently, I am Professor of Obstetrics and Gynecology, Virginia Commonwealth University School of Medicine & George Washington University Professor, Cell Biology & Anatomy, Graduate College, OUHSC, and Vice Chair, Gynecologic Subspecialties, Inova Fairfax Hospital Women's Center. Previously, I was Professor and Section Chief of Female Pelvic Medicine & Reconstructive Surgery and a Professor of Cell Biology and Anatomy at the University of Oklahoma Health Sciences Center.

I was recruited to the University of Oklahoma Health Sciences Center in 2002 as the first fellowship trained physician in Female Pelvic Medicine and Reconstructive Surgery in Oklahoma. Prior to settling in Oklahoma, I obtained my Bachelor degree from the University of Washington in Seattle, Medical Degree from Tufts University in Boston,

professional time. I have removed a significant number of mesh and TVT-O devices since its introduction in 2003, primarily for pain and erosion.

III. SUMMARY OF OPINIONS

1. Mesh complications are unlike those seen with other pelvic surgery in terms of onset, frequency, severity, character, and responsiveness to treatment.
2. Three-dimensional endovaginal ultrasound (EVUS) is a reliable, reproducible, and well-accepted method for assessing pelvic floor conditions, including mesh complications.
3. Mesh complications, including those resulting from transobturator slings, are associated with distinct findings on EVUS.
4. Mesh findings on EVUS include deformation (flat, folding, prominence or convoluted, etc.), shrinkage and contraction, and residual mesh.
5. Mesh contraction (defined by IUGA/ICS as shrinkage or reduction in size) is a well-known occurrence, can be detected by EVUS, and has clinical consequences.
6. The lateral portions of the Gynecare TVT-O of mesh devices are difficult, if not impossible to remove, even with the aid of advanced imaging and surgical skill, and result in significant morbidity for patients.
7. The Gynecare TVT-O is associated with an unacceptably high rate of chronic pain.
8. EVUS evaluation combined with physical examination provides objective evidence of the mechanism and cause of mesh-related symptoms.
9. In a woman presenting with groin pain and/or vaginal/mesh pain and sexual pain following insertion of the TVT-O device, a device-related condition is, more likely than not, the most likely diagnosis on the list of differential diagnoses.
10. In a woman presenting with groin pain and/or vaginal/mesh pain and sexual pain following placement of the TVT-O device, these symptoms are, more likely than not, associated with the material and placement flaws of the TVT-O described in this report.
11. The surgical management of mesh complications requires advanced training and specialized expertise.
12. Timely recognition and referral of mesh complications is of utmost importance to prevent prolonged suffering of patients.

When one looks at the older urogynecology textbooks, the complications of surgical procedures were mostly limited to postoperative medical complications such as postoperative bleeding, pulmonary embolus, myocardial infarctions, and deep venous thrombosis. With the introduction of synthetic materials and mesh kits into vaginal reconstructive surgery over the past decade, unprecedented and unexpected complications have occurred. These are often difficult to manage and require innovative solutions.¹

The placement of mesh increased rapidly in POP and stress urinary incontinence surgery; however, many complications occurred due to inappropriate techniques dictated by the devices, and many complications were recognized too late and were poorly managed. Ironically, in an effort to avoid bladder injuries associated with retropubic slings which were reversible, manufacturers resorted to a transobturator approach which came with its own set of complications which were not reversible. Many of these techniques, including the Gynecare TVT-O, placed mesh through muscles and densely innervated areas where gynecologic surgeons were not accustomed to operating. Complications unique to mesh (vaginal mesh extrusion, urinary tract erosion, mesh contraction, and chronic pain conditions) have been reported with increasing frequency.² Some of these complications are new and unique and require innovative surgeries that may or may not correct the problem. Symptoms of suspected vaginal mesh complications include vaginal discharge and/or bleeding, dyspareunia, pelvic pain, and recurrent urinary tract infections.

¹ Giulio Santoro, MD, Pawel Wiczorek, MD, and S. A. Shobeiri, MD. *Endovaginal Three Dimensional Sonography*. Pelvic Floor Disorders 2010.

² Abed, H., et al. (2011). "Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials: a systematic review." *Int Urogynecol J* 22(7): 789-798; Manonai, J., et al. (2015). "Clinical and ultrasonographic study of patients presenting with transvaginal mesh complications." *Neurourol Urodyn*.

separation).²⁰ Although there is one article in the medical literature by Dietz that questions the evidence for mesh contraction, the methodology in this publication is seriously flawed and does not represent generally held opinions.²¹

There are symptoms and conditions that are unique to mesh. For example, exposure and erosion are only seen with synthetic mesh devices. There are also pain syndromes that are unique to mesh. These are often associated with characteristic findings on ultrasound and pelvic examination. When a patient presents with vaginal pain and sexual pain following a mesh procedure, this condition, more likely than not, is caused by mesh and, more likely than not, is mediated by one or more of the mechanisms discussed in this report. The reason is that mesh produces a unique constellation of symptoms that are characteristic of the presence of mesh and virtually not seen in any other setting. Although a differential diagnosis requires looking at all possible explanations for a given constellation of symptoms, there are very few, if any, other medical conditions that produce the same symptoms as mesh – especially when considered in aggregate.²²

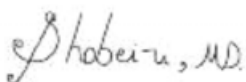
²⁰ *Id.*

²¹ Dietz, H. P. E., M.; Shek, K. L. (2011). "Mesh contraction: myth or reality?" Am J Obstet Gynecol 204(2): 173 e171-174.

²² FDA Safety Communication. UPDATE on serious complications associated with transvaginal placement of surgical mesh for pelvic organ prolapse. Silver Spring, MD: Food and Drug Administration (US), Center for Devices and Radiological Health. Available at <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm262435.htm>; Rogo-Gupta, L. and S. Raz Pain Complications of Mesh Surgery. Complications of Female Incontinence and Pelvic Reconstructive Surgery. H. B. Goldman: 87-105; Lee, D., et al. (2014). "Meshology: a fast-growing field involving mesh and/or tape removal procedures and their outcomes." Expert Rev Med Devices: 1-16; Novara, G., et al. (2010). "Updated systematic review and meta-analysis of the comparative data on colposuspensions, pubovaginal slings, and midurethral tapes in the surgical treatment of female stress urinary incontinence." Eur Urol 58(2): 218-238; Bako, A. and R. Dhar (2009). "Review of synthetic mesh-related complications in pelvic floor reconstructive surgery." Int Urogynecol J Pelvic Floor Dysfunct 20(1): 103-111; Hansen, B. L., et al. (2014). "Long-term follow-up of treatment for synthetic mesh complications." Female Pelvic Med Reconstr Surg 20(3): 126-130; Dunn, G. E., et al. (2014). "Changed women: the long-term impact of vaginal mesh complications." Female Pelvic Med Reconstr Surg 20(3): 131-136; Abbott, S., et al. (2014). "Evaluation and management of complications from synthetic mesh after pelvic reconstructive

reasonable degree of medical certainty that the injuries and complications that I have personally observed, diagnosed and treated associated with the TVT-O are directly attributable to the defective design of these products as described previously. Because of the unique complications, especially chronic pain, associated with the TVT-O, the difficulty removing when problems arise, and the availability of safer alternatives, it is my opinion that the risks of the TVT-O outweigh the benefits. This is why I, and many of my colleagues in academic centers, no longer use TVT-O in practice. However, I continue to see complications from these devices placed by community doctors. As we have reported, some community doctors, who frequently rely on information from medical device companies, may lack an appreciation of the nature and severity of mesh-induced complications. We have shown that patients who have had mesh complications typically don't follow-up with the physician who performed the initial surgery. As such the physicians may remain unaware of the number or the extent of complications arising from their TVT-O procedures.

Dated: February 1, 2016



S. Abbas Shobeiri, M.D.

LITERATURE RELIED UPON

Attached as **Exhibit B**.

FEE SCHEDULE

Dr. Shobeiri's standard rate is \$750/hr; for expert witness testimony \$6,000/day plus travel and lodging expenses.